REMARKS

This application has been reviewed in light of the Office Action mailed on September 24, 2003. Claims 1-3, 6, 9-11 and 19-29 are pending in the application with Claims 1, 9 and 22 being in independent form. By the present amendment, Claims 6, 11 and 28 have been amended. No new matter or issues are believed to be introduced by the amendments.

In the Office Action, Claims 1-3, 6, 9-11 and 19-29 were rejected under 35 U.S.C. §112, first paragraph.

With respect to independent Claims 1, 9 and 22, the Office Action states that the specification fails to teach specific parameters for how the created standing wave/radiation pressure provides a bactericidal and therapeutic effect for decreasing the healing time of a wound without undue experimentation. It is respectfully submitted that standing waves created between a distal end of an ultrasonic transducer and a wound according to the equation $n \times \lambda/2$ create radiation pressure. The radiation pressure has been shown to provide bactericidal and therapeutic effects which result in a decrease in the healing time of a wound. That is, the bactericidal and therapeutic effects which result in a decrease in the healing time of the wound are intrinsic properties of ultrasonic standing waves. Ultrasonic standing waves are known to physiologically and morphologically affect bacteria cells. See, for example, the accompanying articles entitled, "Viability of Yeast Cells in Well Controlled Propagating and Standing Ultrasonic Plane Waves," Radel et al., *Ultrasonics*, vol. 38, pages 633-637, 2000 (describes controlling the spatial organization of yeast cells (bacteria) using both standing and propagating ultrasonic waves); and "Breakdown of Immobilisation/Separation and Morphology Changes of Yeast Suspended in Water-Rich Ethanol Mixtures Exposed to Ultrasonic Plane Standing Waves," Radel et al.,

Bioseparation, vol. 9, pages 369-377, 2001 (describes physiological/morphological changes of suspended yeasts when exposed to well-defined ultrasonic standing waves, as well as propagating ultrasonic waves). Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, with respect to Claims 1, 9 and 22 is respectfully requested.

With respect to dependent Claim 6, this claim has been amended to overcome the rejection under 35 U.S.C. §112, second paragraph, by deleting the phrase "or other medicant." With respect to the rejection of this claim under 35 U.S.C. §112, first paragraph, it is commonly known to apply gels and drugs to a wound surface and what type of gels or drugs one can apply to the wound surface. The Examiner states that with respect to Claim 6 the specification does not teach how, when, or what gel, drug, or medicament to apply to the wound to achieve therapeutic effects without undue experimentation. It is respectfully submitted that Claim 6 does not recite that the application of a gel or drug achieves therapeutic effects. Claim 6 merely recites that in a prior step, or prior to the step of positioning an ultrasound transducer, a gel or drug is applied to the wound. The application of a gel or drug to a wound surface is commonly known and Applicant's disclosure adequately describes creating standing waves between an ultrasound transducer's distal end and a wound surface having a gel or drug applied thereon. Accordingly, withdrawal of the rejections under 35 U.S.C. §112, first and second paragraphs, with respect to Claim 6 is respectfully requested.

With respect to Claim 26, the specification teaches that blood clots are dissolved within a blood vessel by creating cavitation inside the blood vessel by using ultrasound standing waves. See page 6, first full paragraph in conjunction with Figure 5. Cavitation is created inside the blood vessel by creating standing waves between the blood vessel's side wall/radial surface and a

transducer tip of an ultrasound transducer as shown by Figure 5. It is respectfully submitted that Claim 26 does not recite that the dissolving of blood clots provides a bactericidal effect. Claim 26 merely recites that the therapeutic effect is selected from a group consisting, among other things, dissolving blood clots. The specification teaches that ultrasound energy can be used to dissolve blood clots. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, with respect to Claim 26 is respectfully requested.

With respect to Claim 27, Applicant agrees with the Examiner that the specification does not teach what drug may be successfully penetrated through the surface of the wound using ultrasound standing waves. However, Applicant respectfully submits that one having ordinary skill in the art would know what drugs can be successfully penetrated through the surface of the wound using ultrasound standing waves. See, for example, the accompanying articles entitled, "Ultrasound-Mediated Transdermal Protein Delivery," Mitragotri et al., *Science*, vol. 269, pages 850-853, August 11, 1995 (describes the penetration of proteins through the human skin using low-frequency ultrasound); and "Transdermal Delivery of Insulin by Ultrasonic Vibration," Tachibana et al., *J. Pharm. Pharmacol.*, vol. 43, pages 270-271, April 1991 (describes the penetration of insulin through the skin of hairless mice using ultrasonic vibration). Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, with respect to Claim 27 is respectfully requested.

The other dependent claims, namely, Claims 2, 3, 10, 20-25 and 29, depend from either Claim 1, 9 or 22, and therefore include the limitations of either Claim 1, 9 or 22. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, with respect to Claims 2, 3, 10, 20-25 and 29 is respectfully requested.

Claims 11 and 28, as with Claim 6 addressed above, were rejected under 35 U.S.C. §112, second paragraph. Claims 11 and 28 were amended to overcome the rejection under 35 U.S.C. §112, second paragraph. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, with respect to Claims 11 and 28 is respectfully requested.

Claims 1, 2, 9-11, 22, 23, 26 and 28 were rejected under 35 U.S.C. §102(b) as being anticipated over U.S. Patent No. 5,431,663 issued to Carter on July 11, 1995 ("Carter"). The rejection is respectfully traversed.

Carter does not disclose or suggest the creation of an ultrasonic standing wave between the surface of a wound and a distal radiation surface of an ultrasound transducer, where the ultrasound standing wave creates radiation pressure for providing a bactericidal and a therapeutic effect to the wound for decreasing the healing time for the wound, as recited by Applicant's Claim 1, and similarly recited by Applicant's Claims 9 and 22.

Carter teaches how to create constant ultrasonic vibrational amplitude at the radiator/tip site by changing the length of piezoelectric crystal for preventing loss of acoustic power (see column 4, lines 33-48). According to Carter, the creation of sufficient length of piezoelectric crystal avoids the loss of amplitude at resonance (column 4, lines 50-68), due to the occurrence of ultrasound standing waves **inside** of the device, between rear face 36 of piezocrystal and radiating surface 48 of guide/amplifier 58 (see Figure 2), and not between a distal radiation surface and the surface of wound as recited by Applicant's Claims 1, 9 and 22. Carter teaches using sufficient piezoelectric crystal length from 1.25 to 12.5 mm in an operating frequency range of 50kHz to 1.3MHz to maintain and cause cavitation for disruption and liquefaction of blood clots and plaque when the device is placed inside a blood vessel, and not for decreasing the

healing time of a wound as recited by Applicant's Claims 1, 9 and 22. Further, Applicant's Claims 1, 9 and 22 do not recite placement of an ultrasound transducer inside a blood vessel. In the contrary, Applicant's claims require the ultrasound transducer to be placed at a distance d from the surface of the wound and not inside a blood vessel. The radiation pressure created by Applicant's invention as recited by Claims 1, 9 and 22 is transmitted through the tissue layer and dissolves blood clots within the blood vessel. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 1, 9 and 22 are respectfully requested.

Claims 2, 10, 11, 23, 26 and 28 depend from either Claim 1, 9 or 22, and therefore include the limitations of either Claim 1, 9 or 22. Accordingly, for the same reasons given for Claims 1, 9 and 22, Claims 2, 10, 11, 23, 26 and 28 are believed to contain patentable subject matter. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) and allowance of Claims 2, 10, 11, 23, 26 and 28 are respectfully requested.

Claims 1, 2, 9, 10, 19-25 and 29 were rejected under 35 U.S.C. §102(b) as being anticipated over U.S. Patent No. 6,007,499 issued to Martin et al. on December 28, 1999 ("Martin et al."). The rejection is respectfully traversed.

Martin et al. does not disclose or suggest the creation of an ultrasonic standing wave between the surface of a wound and a distal radiation surface of an ultrasound transducer, where the ultrasound standing wave creates radiation pressure for providing a bactericidal and a therapeutic effect to the wound for decreasing the healing time for the wound, as recited by Applicant's Claim 1, and similarly recited by Applicant's Claims 9 and 22.

Martin et al. teaches placing an apparatus in contact with the patient and emitting high intensity focused ultrasound ("HIFU") to form cauterized tissue regions **within the body** prior to

surgical incision. At best, Martin shows superposition of incident and reflected ultrasound waves inside of the tissue, not between a distal radiation surface and a surface of the wound, as recited by Applicant's Claims 1, 9 and 22. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 1, 9 and 22 are respectfully requested.

Claims 2, 10, 19-21, 23-25 and 29 depend from either Claim 1, 9 or 22, and therefore include the limitations of either Claim 1, 9 or 22. Accordingly, for the same reasons given for Claims 1, 9 and 22, Claims 2, 10, 19-21, 23-25 and 29 are believed to contain patentable subject matter. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) and allowance of Claims 2, 10, 19-21, 23-25 and 29 are respectfully requested.

Claims 3 and 24; Claims 20 and 25; and Claims 6 and 27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Carter '663 or Martin et al. '499; over Carter '663; and over Carter '663 in view of Brisken '811, respectively.

Claims 3, 6, 20, 24, 25 and 27 depend from either Claim 1 or 22, and therefore include the limitations of either Claim 1 or 22. Accordingly, for the same reasons given for Claims 1 and 22, Claims 3, 6, 20, 24, 25 and 27 are believed to contain patentable subject matter.

Additionally, with respect to Carter '663 and Brisken '811, these patents teach the placement of an ultrasound transducer within a blood vessel. As mentioned above, Carter '663 uses the phenomena of the occurrence of standing waves inside of a device having a piezocrystal to increase amplitude and prevent loss of acoustic power. Brisken '811 teaches the use of two tubular transducer assemblies in a catheter body to create standing waves between radial radiation surface (not distal radiation surface) of transducer and vascular wall. The standing waves created between the radial radiation surface and vascular wall produce a shearing effect on

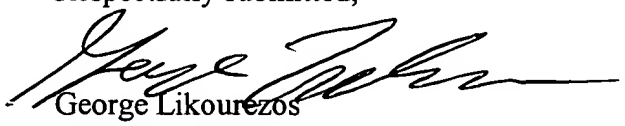
the vascular wall for dissolving clots or plaque in front of the transducer (no standing waves are created in front of the transducer). In the contrary, Applicant's independent Claims 1, 9 and 22 which are further limited by dependent Claims 3, 6, 20, 24, 25 and 27 recite the positioning of an ultrasound transducer at a distance d from the surface of the wound for creating standing waves between a distal radiation surface of the ultrasound transducer and the surface of the wound. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) and allowance of Claims 3, 6, 20, 24, 25 and 27 are respectfully requested.

With respect to the obviousness-type double patenting rejection of Claims 1-3, 9-11, 19-25 and 27 over U.S. Patent No. 6,478,754, Applicant agrees with the Examiner's assessment as outlined on paragraph 8 of the Office Action. Therefore, Applicant submits a terminal disclaimer along with this amendment in compliance with 37 C.F.R. Sec. 1.321(c), since the present application and U.S. Patent No. 6,478,754 are commonly owned.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims presently pending in the application, namely, Claims 1-3, 6, 9-11 and 19-29, are believed to be in condition for allowance and patentably distinguishable over the art of record.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicant's undersigned attorney at (631) 501-5706.

Respectfully submitted,



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